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Carolyn Roberts
Name of applicant, assignee
or Registered Representative
Carolyn Roberts
Signature

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Date of Signature

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Patent
Case No. P-191

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Clark M. Whitehead et al.)
Serial No.: 09/938,160) Examiner: Not Yet Assigned
Filed: August 23, 2001) Art Unit: Not Yet Assigned
For: METHODS FOR TREATMENT OF)
SCLERODERMA)

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Pursuant to the obligation under 37 C.F.R. § 1.56 and in conformance with 37 C.F.R. §§ 1.97-1.99, Applicants hereby submit the following documents for consideration by the Examiner. A copy of each has been enclosed along with two copies of the PTO-1449 form.

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REMARKS

Applicants request that these references be made of record in this case, and that the Examiner indicate his review of these references by initialing and returning one copy of the PTO form enclosed.

This Information Disclosure Statement is being submitted before the mailing of the first Office Action on the merits pursuant to 37 C.F.R. § 1.97.

Respectfully submitted,



Robert W. Stevenson

Reg. No. 31064

Attorney for Applicants

Dated: September 4, 2001

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FORM PTO-1449

SERIAL NO.

09/938,160

CASE NO.

P-191

**LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE STATEMENT**

(use several sheets if necessary)

FILING DATE

AUGUST 23, 2001

GROUP ART UNIT

NOT YET ASSIGNED

APPLICANT(S): WHITEHEAD ET AL.

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A1	3,031,450	4/24/62	Fischer et al.		
	A2	3,161,654	12/15/64	Shen		
	A3	3,312,730	4/4/67	Winter et al.		
	A4	3,322,755	5/30/67	Roch et al.		
	A5	3,325,358	6/13/67	Winter et al.		
	A6	3,532,752	10/6/70	Shen		
	A7	3,642,785	2/15/72	Shen et al.		
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	A14	EP 0 293 063 B1	3/18/92	EPO		
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	A16	EP 0 349 239 A2	1/3/90	EPO		
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EXAMINER
INITIAL

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

	A19	Ahmad F. et al., IL-3 ad IL-4 Activate Cyclic Nucleotide Phosphodiesterases 3 (PDE3) and 4 (PDE4) by Different Mechanisms in FDCP2 Myeloid Cells, J. Immunology Vol. 162, Part 8, pp. 4864-4875 (Apr 15 1999).
	A20	Boven LA et al., Macrophage inflammatory protein-1 alpha (MIP-1alpha), MIP-1beta, and RANTES mRNA semiquantification and protein expression in active demyelinating multiple sclerosis (MS) lesions, <i>Clin. Exp. Immunol.</i> 2000 Nov.; 122(2): 257-63 (Abstract Only).
	A21	Cooper N. et al., A comparison of the inhibitory activity of PDE4 inhibitors on leukocyte PDE4 activity in vitro and eosinophil trafficking in vivo, <i>British Journal of Pharmacology</i> (1999) 126, pp. 1863-1871.
	A22	Czirjak L. et al., Investigation of the alveolar macrophages and T lymphocytes in 15 patients with systemic sclerosis, <i>Clin Rheumatology</i> 1999; 18(5), pp. 357-363 (Abstract Only).
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	A24	Duggan, D.E. et al., Identification of the Biologically Active Form of Sulindac, <i>J. Pharm. & Exper. Therap.</i> , Vol. 201, No. 1, pp.8-13 (1977).

EXAMINER

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	A69	Hollander AP et al., Expression of hypoxia-inducible factor 1 alpha by macrophages in the rheumatoid synovium: implications for targeting of therapeutic genes to the inflamed joint, <i>Arthritis Rheum.</i> 2001 Jul; 44(7): 1540-4 (Abstract Only).				
	A70	Imahashi K. et al., Type IV Phosphodiesterase Inhibitor Suppresses Insulin-Dependent Myocardial Glucose Uptake, <i>Clin Exp Pharmacol Physiol</i> 2001 Apr;28(4), pp. 290-291 (Abstract Only)				
	A71	Ishikawa O. et al., Macrophage infiltration in the skin of patients with systemic sclerosis, <i>J. Rheumatology</i> 1992 Aug; 19(8), pp. 1202-1206 (Abstract Only).				
	A72	Kapur S. et al., Expression of Nitric Oxide Synthase in Skeletal Muscle, Diabetes, Vol. 46, Nov. 1997, pp. 1691-1700.				

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FORM PTO-1449

SERIAL NO.

09/938,160

CASE NO.

P-191

**LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE STATEMENT**
(use several sheets if necessary)

FILING DATE

AUGUST 23, 2001

GROUP ART UNIT

NOT YET ASSIGNED

APPLICANT(S): WHITEHEAD ET AL.

REFERENCE DESIGNATION

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A73	5,885,834	3/23/99	Epstein	
	A74	5,902,827	5/11/99	Pamukcu et al.	
	A75	5,922,595	7/13/99	Fisher et al.	
	A76	5,942,520	8/24/99	Pamukcu et al.	
	A77	5,948,911	9/7/99	Pamukcu et al.	
	A78	5,958,982	9/28/99	Pamukcu et al.	
	A79	5,990,117	11/23/99	Pamukcu et al.	
	A80	5,998,463	12/7/99	Hulin et al.	
	A81	6,008,215	12/28/99	Flockerzi	
	A82	6,015,677	1/18/00	Beavo et al.	
	A83	6,034,099	3/7/00	Pamukcu et al.	
	A84	6,037,345	3/14/00	Pamukcu et al.	
	A85	6,046,199	4/4/00	Pamukcu et al.	

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FOREIGN PATENT DOCUMENTS


EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES NO
	A86	SHO 61-106521	5/24/86	Japan	
	A87	WO 01/04099 A1	1/18/01	PCT	
	A88	WO 00/12501	3/9/00	PCT	
	A89	WO 00/26201	5/11/00	PCT	
	A90	WO 00/23091	4/27/00	PCT	

EXAMINER INITIAL	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)				
	A91	Kelly J. et al., Characterization of phosphodiesterase 4 in guinea-pig macrophages: multiple activities, association states and sensitivity to selective inhibitors, British Journal of Pharmacology (1998) 124, PP. 129-140.			
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	A94	Lee MS et al., A comparative immunohistochemical study of lichen planus and discoid lupus erythematosus, <i>Australas J. Dermatol.</i> 1996 Nov.; 37(4): 188-92 (Abstract Only).			
	A95	McPherson M.A. et al., A cyclic nucleotide PDE5 inhibitor corrects defective mucin secretion in submandibular cells containing antibody directed against the cystic fibrosis transmembrane conductance regulator protein, FEBS Letters 464 (1999), pp. 48-52.			
	A96	Mery P.F. et al., Erythro-9-(2-hydroxy-3-nonyl)adenine inhibits cyclic GMP-stimulated phosphodiesterase in isolated cardiac myocytes, Mol. Pharmacology 1995 Jul;48(1), pp. 121-130 (Abstract Only)			

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		AUGUST 23, 2001	NOT YET ASSIGNED
		APPLICANT(S): WHITEHEAD ET AL.	

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	A97	6,046,206	4/4/00	Pamukcu et al.		
	A98	6,046,216	4/4/00	Piazza et al.		
	A99	6,060,477	5/9/00	Piazza et al.		
	A100	6,066,634	5/23/00	Sperl et al.		
	A101	6,069,240	5/30/00	Wigler et al.		
	A102	6,071,934	6/6/00	Sperl et al.		
	A103	6,077,842	6/20/00	Pamukcu et al.		
	A104	6,080,540	6/27/00	Wigler et al.		
	A105	6,080,742	6/27/00	Germann et al.		
	A106	6,080,772	6/27/00	Tang et al.		
	A107	6,100,025	8/8/00	Wigler et al.		
	A108	6,107,295	8/22/00	Rochus et al.		
	A109	6,124,303	9/26/00	Pamukcu et al.		

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES NO
	A110	WO 00/26208	5/11/00	PCT		
	A111	WO 00/27861	5/18/00	PCT		
	A112	WO 00/42017	7/20/00	PCT		
	A113	WO 00/42018	7/20/00	PCT		
	A114	WO 00/42019	7/20/00	PCT		

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	A115 Méry, Pierre-François et al., EHNA as an Inhibitor of PDE2: A Pharmacological and Biochemical Study in Cardiac Myocytes, Phosphodiesterase Inhibitors (1996), pp. 81-88.
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	A117 Niebauer J. et al., Local L-Arginine Delivery After Balloon Angioplasty Reduces Monocyte Binding and Induces Apoptosis, Circulation 1999;100, pp. 1830-1835.
	A118 Odoux C. et al., Endothelin-1 secretion by alveolar macrophages in systemic sclerosis, Am. J. Respir. Crit. Care Med. 1997 Nov;156(5), pp. 1429-1435 (Abstract Only).
	A119 Ostensen M. et al., Nonsteroidal anti-inflammatory drugs in systemic lupus erythematosus, Lupus (2001) 10, pp. 135-139.
	A120 Piazza G.A. et al., Antineoplastic Drugs Sulindac Sulfide and Sulfone Inhibit Cell Growth by Inducing Apoptosis, Cancer Research 55, Jul 15 1995, pp. 3110-3116.

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FORM PTO-1449	SERIAL NO. 09/938,160	CASE NO. P-191
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)	FILING DATE AUGUST 23, 2001	GROUP ART UNIT NOT YET ASSIGNED
	APPLICANT(S): WHITEHEAD ET AL.	

REFERENCE DESIGNATION U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A121 6,133,271	10/17/00	Pamukcu et al.		
	A122 6,143,746	11/7/00	Daugan et al.		
	A123 6,143,759	11/7/00	Flockerzi		
	A124 6,143,765	11/7/00	Tang et al.		
	A125 6,143,777	11/7/00	Jonas et al.		
	A126 6,169,090	1/2/01	Dyke et al.		
	A127 6,174,884	1/16/01	Haning et al.		
	A128 6,187,779	2/13/01	Pamukcu et al.		
	A129 6,200,771	3/13/01	Liu et al.		
	A130 6,200,980	3/13/01	Piazza et al.		
	A131 6,207,666	3/27/01	Piazza et al.		
	A132 6,211,177	4/3/01	Sperl et al.		
	A133 6,211,220	4/3/01	Pamukcu et al.		

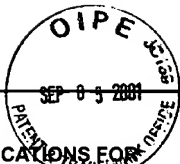
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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES NO
	A134 WO 00/42034	7/20/00	PCT		
	A135 WO 00/59890	10/12/00	PCT		
	A136 WO 00/64424	11/2/00	PCT		
	A137 WO 99/65880	11/23/99	PCT		
	A138 WO 98/19679A1	5/14/98	PCT (Claims Only)		

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	A139	Reis E. et al., Sulindac inhibits neointimal formation after arterial injury in wild-type and apolipoprotein E-deficient mice, PNAS 97(23): pp. 12764-12769.
	A140	Rice P.L. et al., Inhibition of extracellular signal-regulated kinase 1/2 phosphorylation and induction of apoptosis by sulindac metabolites, Cancer Research 2001, Feb 15;61(4), pp. 1541-1547 (Abstract Only).
	A141	Soh, Jae-Won et al., Cyclic GMP Mediates Apoptosis Induced by Sulindac Derivatives via Activation of c-Jun NH ₂ -Terminal Kinase 1, Clinical Cancer Research Vol. 6, pp. 4136-4141, October 2000.
	A142	Soh, Jae-Won et al., Protein Kinase G Activates the JNK1 Pathway via Phosphorylation of MEKK1, The Journal of Biological Chemistry, Vol. 276, No. 19, pp. 16406-16410 (2001).
	A143	Thompson, W.J. et al., Exisulind Induction of Apoptosis Involves Guanosine 3',5'-Cyclic Monophosphate Phosphodiesterase Inhibition, Protein Kinase G Activation, and Attenuated β -Catenin, Cancer Research 60, pp. 3338-3342, July 1, 2000.
	A144	Tien, Xiao-Ying, et al., Activation of the Cystic Fibrosis Transmembrane Conductance Regulator by cGMP in the Human Colonic Cancer Cell Line, Caco-2, The Journal of Biological Chemistry, Vol. 269, No. 1, pp. 51-54 (1994).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A145	6,232,312	5/15/01	Pamukcu et al.		
	A146	6,235,742	5/22/01	Bell et al.		
	A147	6,235,776	5/22/01	Pamukcu et al.		
	A148	6,235,782	5/22/01	Pamukcu et al.		
	A149	6,239,136	5/29/01	Pamukcu et al.		
	A150	6,251,904	6/26/01	Bunnage et al.		
	A151	6,255,303	7/3/01	Sterk et al.		
	A152	6,255,456	7/3/01	Fisher et al.		
	A153	6,258,833	7/10/01	Martins et al.		
	A154	6,268,372	7/31/01	Pamukcu et al.		

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES	NO
	A155	WO 98/17668	4/30/98	PCT			
	A156	WO 98/14448	4/9/98	PCT			
	A157	WO 98/06722	2/19/98	PCT			
	A158	WO 97/24334	7/10/97	PCT			
	A159	WO 97/03985	2/6/97	PCT			

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	A160	Tsukahara T et al., Cytophagic histiocytic panniculitis in systemic lupus erythematosus, <i>Hiroshima J. Med. Sci.</i> , 1995 Mar; 44(1): 13-6 (Abstract Only).
	A161	Waddel W. R. et al., Sulindac for Polyposis of the Colon, <i>The American Journal of Surgery</i> , Vol. 157, Jan. 1989, pp. 175-179.
	A162	Waddel W. R. et al., Sulindac for Polyposis of the Colon, <i>Journal of Surgical Oncology</i> , 24: pp. 83-87 (1983).
	A163	Weyand CM and Goronzy JJ, HLA polymorphisms and T cells in rheumatoid arthritis, <i>Int. Rev. Immunol.</i> 1999; 19(1-2):37-39 (Abstract Only).
	A164	Wilder R.L. et al., Hormonal regulation of tumor necrosis factor-alpha, interleukin-12 and interleukin-10 production by activated macrophages. A disease-modifying mechanism in rheumatoid arthritis and systemic lupus erythematosus?, <i>Ann. NY Acad. Sci</i> 1999 June 22;876, pp. 14-31 (Abstract Only).

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